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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,778	09/18/2003	Alain Goossens	2676-6085US	8721
24247	7590	08/11/2006	EXAMINER	
TRASK BRITT P.O. BOX 2550 SALT LAKE CITY, UT 84110			KALLIS, RUSSELL	
			ART UNIT	PAPER NUMBER

1638

DATE MAILED: 08/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/666,778	GOOSSENS ET AL.	
	Examiner	Art Unit	
	Russell Kallis	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 15-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I claims 1-14, 15-18 in the reply filed on 5/22/2006 is acknowledged.

Claim 14 is withdrawn. Claims 1-13 and 15-18 are examined.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim is broadly drawn to fragments and variants from polynucleotides that have at least 91 sequence identity to SEQ ID NO: 1 or at least 91% sequence identity to a sequence that encodes SEQ ID NO: 2 and that induce and/or enhance the production or secretion of at least one secondary metabolite in plants or plant cells.

Applicant describes SEQ ID NO: 1 encoding SEQ ID NO: 2.

Applicant does not describe any variant or fragment from a polynucleotide having at least 91% sequence identity to SEQ ID NO: 1 or from a polynucleotide encoding SEQ ID NO: 2 that induce or enhance the production or secretion of at least one secondary metabolite in a plant cell or plant.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. The court stated that, “A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus.” *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of variants or fragments from a polynucleotide having at least 91% sequence identity to SEQ ID NO: 1 or from a polynucleotide encoding SEQ ID NO: 2 that induce or enhance the production or secretion of at least one secondary metabolite in a plant cell or plant. Applicants only describe SEQ ID NO: 1 encoding SEQ ID NO: 2. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of claimed variants and fragment. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for inducing or enhancing the production or secretion of a secondary metabolite in a plant cell or plant, it remains unclear what features identify the broadly claimed genus of fragments or variants. Since the genus of variants or fragments from a polynucleotide having at least 91% sequence identity to SEQ ID NO: 1 or from a polynucleotide encoding SEQ ID NO: 2 that induce or enhance the production or secretion of at least one secondary metabolite in a plant cell or plant has not been described by specific structural features, the specification fails to provide an adequate written description to support the breadth of the claims.

Sequences that are 91% complementary to SEQ ID NO: 1 or SEQ ID NO: 2 encompass naturally occurring allelic variants, mutants and fragment of SEQ ID NO: 1, as well as sequences encoding proteins having no known activity with respect to inducing or enhancing the production or secretion of at least one secondary metabolite, of which Applicant is not in possession.

Accordingly, the specification fails to provide an adequate written description to support the genus of isolated polynucleotide fragments and variants having 91% sequence identity to SEQ ID NO: 1 or the polynucleotide encoding SEQ ID NO: 2 encompassed by the percent identity language as set forth in the claims. (See Written Description guidelines published in Federal Register/Vol. 66, No.4/Friday, January 5, 2001/Notices: p.1099-1111).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Theodoulou F. Biochemica et Biophysica Acta; 2000, 1465, pp. 79-103 in view of Dudler R. *et al.* Journal of Biological Chemistry; 25 March 1992, Vol. 267, No. 9 pp. 5582-5888.

The claims are broadly drawn to processes of enhancing secretion of a plant secondary compound by transforming a plant or plant cell with a vector comprising a gene encoding an ABC-transporter; and plants and plant cells thereof.

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Theodoulou teaches ABC transporter genes from plants that have strong similarity to MDR proteins from other species and suggests a role of the plant homologues in the secretion or sequestering of *vinca* alkaloid and the alkaloid taxol and suggests a strategy for screening transformed plants and plant cells for determining the specific transport function (section 5.2 page 86).

It would have been obvious at the time of Applicant's filing to take a plant ABC transporter gene that encoded a protein that had similar structural motifs to the human MRD ABC transporter and test for induced or enhanced production or secretion of an alkaloid such as the *vinca* alkaloid or taxol to determine the function of the plant MDR homologue. One of ordinary skill in the art would have been motivated by the teaching of Theodoulou that taxol and other plant secondary metabolites are substrates or bind MDR ABC transporter proteins and would be useful in the art of bioengineering secondary product production in plants or plant cells that produce taxol, *vinca* alkaloid or other plant secondary compounds; and have had a reasonable expectation of success given that transgenic strategies for evaluating the specific function of plant ABC transporter genes were within the reach of one of ordinary skill and that non-plant alkaloid transporters and methods of transforming plants and maintaining plant cell cultures for the production of secondary metabolites were known in the art.

All claims are rejected.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Russell Kallis Ph.D.
August 7, 2006

RUSSELL P. KALLIS, PH.D.
PRIMARY EXAMINER

Russell Kallis